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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,805	03/02/2002	Valeri V. Golovlev		2639

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EXAMINER	
YANG, NELSON C	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/086,805	GOLOVLEV, VALERI V.	
	Examiner	Art Unit	
	Nelson Yang	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) *1-6 and 9-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-8, 12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/2/2002*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims 7-16 in the paper submitted February 10, 2004 is acknowledged. The traversal is on the ground(s) that there would be no serious burden on the examiner to examine all the claims at one time. This is not found persuasive because examiner has shown that the method can be performed by another materially different device. Furthermore, as can be seen in the claims, the method of group II do not require all the limitations recited by group I, in particular those recited in claims 2-5. Therefore, it would indeed pose an undue burden on the examiner to examine the claims of group I in addition to the invention of group II.

2. Applicant's election of oligonucleotides in the paper submitted February 10, 2004, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Claims 1-6 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper submitted February 10, 2004.

4. Claims 9-11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in paper submitted on February 10, 2004.

5. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7, 8, 12-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. The term "gradually" in claim 7 is a relative term which renders the claim indefinite. The term "gradually" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Furthermore, it is unclear how the term "gradual" is used in reference to the increasing or decreasing temperature, whether it is intended to refer to the rate of change, type of change (i.e. as opposed to step changes), range of change, or by some other means, rendering the claim indefinite. This is also applicable to the use of the term "gradual" in claim 14.

9. Claim 8 recites the limitation "oligonucleotide probes or their analogous equivalent". It is unclear what would constitute being analogous equivalent to an oligonucleotide probe, and applicant fails to further define what would be considered analogous equivalent, rendering the claim indefinite.

10. The remaining claims are indefinite due to their dependence on an indefinite claim

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 7,8, 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hollis et al [US 5,846,708].

Hollis et al teach a method comprising applying a sample to a plurality of test sites having attached probes such that different test sites have probes that bind to different molecular structures, formed on a surface of an integrated circuit array sensor (column 4, lines 41-45), maintaining a constant preprogrammed temperature or running a preprogrammed temperature profile (column 10, lines 18-25), acquiring an electronic signal from a plurality of pixels associated with the test sites (column 4, 60-65), and detecting the amplitude of the signals versus time from the test sites to determine which probes have interacted with an associated target molecular structure (column 7, lines 15-33).

13. With respect to claims 8, the probes can be oligonucleotides or antibodies (column 4, lines 35-41).

14. With respect to claim 12, the detection step can comprise detecting an electronic signal at a constant temperature of the sample substance and the array sensor. Specifically, Hollis et al teach a desired synthesis temperature applied to wells where a reaction is desired (column 13, lines 50-55).

15. With respect to claim 15, the detection step comprises an electronic signal vs time (rate of hybridization) for each probe site (column 7, lines 15-33, column 14, lines 3-19).

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. Claim 13 is rejected under 35 U.S.C. 103(a) as being obvious over Hollis et al [US 5,846,708] in view of Atwood et al [US 5,602,756].

Hollis et al teach a method comprising a detection step comprising detecting an electronic signal during a change of the temperature of the sample substance and the array sensor, as discussed above. Hollis et al do not teach that the change in temperature is stepwise. Atwood et al, however, teach that generally it is desirable to change the sample temperature to the next temperature in the cycle as rapidly as possible for several reasons. First, the chemical reaction has an optimum temperature for each of its stages. Thus, less time spent at nonoptimum temperatures means a better chemical result is achieved. Another reason is that a minimum time for holding the reaction mixture at each incubation temperature is required after each said incubation temperature is reached. These minimum incubation times establish the "floor" or minimum time it takes to complete a cycle. Any time transitioning between sample incubation temperatures is time which is added to this minimum cycle time. Since the number of cycles is fairly large, this additional time unnecessarily lengthens the total time needed to complete the amplification (column 2, lines 57 – column 3, line 5). Therefore, it would have been obvious in the method taught by Hollis et al to have the detection step comprise a stepwise change in

temperature, as suggested by Atwood et al, in order to achieve a better chemical result and to minimize the cycle times.

18. Claims 14 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis et al [US 5,846,708] in view of Ulanovsky [US 5,627,032].

Hollis et al teach a detection step comprises detecting an electronic signal during a change of the temperature of the sample substance and the array sensor as discussed above (column 7, lines 15-33 and column 13, lines 43-47). Hollis et al do not teach a gradual change in temperature. Ulanovsky, however, teaches that it is not always easy to determine the optimal temperature of the composite extension reaction a priori and that a practical way to do so is to decrease the temperature slowly (within a few minutes to a few tens of minutes) through the right range (column 21, lines 1-21). Therefore, it would have been obvious to have a detection step comprising detecting an electronic signal during a gradual change in temperature, as taught by Ulanovsky, in the method of Hollis et al, in order to determine the optimal temperature of the composite extension reaction.

Conclusion

19. No claims are allowed.

20. The following references are also cited as art of interest: Goldberg et al [US 6,203,989], Burkhardt [US 5,501,963], Eggers et al [US 5,532,128].

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nelson Yang whose telephone number is (571) 272-0826. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

22. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nelson Yang
Patent Examiner
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LONG V. LE
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03/13/04